UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/455,683	05/31/1995	GRAEME I. BELL	ARCD:177/WIM	8952

7590 01/05/2004

DAVID L. PARKER
FULBRIGHT & JAWORSKI
600 CONGRESS AVENUE SUITE 2400
AUSTIN, TX 78701

EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/455,683	BELL ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-58,60-62,68-80,97-102,109,112-114,123 and 137-156* is/are pending in the application.

4a) Of the above claim(s) *53-58,60-62 and 68-80* is/are withdrawn from consideration.

5)☒ Claim(s) *109,112-114,123 and 137-150* is/are allowed.

6)☒ Claim(s) *97-102 and 151-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Formal Matters

A. The Amendment filed 9/22/03 has been entered into the record.

B. Claims 53-58, 60-62, 68-80, 97-102, 109, 112-114, 123 and 137-143 are pending. Claims 144-156 have been added. Claims 53-58, 60-62, 68-80 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 97-102, 109, 112-114, 123 and 137-156 are the subject of this Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 97-102 remain rejected and new claims 144-156 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-4 of the Office Action dated 6/17/03. Applicants argue that Applicants' specification provides written description support for full-length human opioid receptors. For example, the background section of the specification provides substantial information pertaining to the structure and function of opioid receptors. specification, page 3, line 20 through page 11, line 8. The major classes of opioid receptors are discussed, including properties of these different classes. Specification, page 3, line 20 through page 5, line 15. Binding properties and structural characteristics of opioid receptors are also discussed. Applicants argue that the specification also discloses a recombinant opioid receptor encoded by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:11. Those of ordinary skill in the art understand that an opioid receptor must have certain functional characteristics. In addition, those of ordinary skill in the art would be familiar with the function of opioid receptors, which is described throughout the specification, as noted above. Thus, functional full-length opioid receptors are fully supported by the specification. required for one of skill in the art to recognize the invention. Applicants further argue that the present invention is drawn to methods of screening a substance for its ability to specifically bind to an opioid receptor by contacting the substance with an opioid receptor polypeptide encoded by a nucleic acid sequence that has all or part of the contiguous bases of SEQ ID NO:11. Thus,.the specification satisfies the written description requirement because it reasonably conveys to one of skill in the art that Applicants had possession of the claimed subject matter. In re Daniels, 144 F.3d 1452, 1456, 46 USPQ 2d 1788, 1790. The process pertains to polynucleotides that are encoded by at least 30 contiguous bases of SEQ ID NO:11. By formulating a rejection for failure to recite the entire sequence of a full-length opioid receptor and making reference to “reach through claims,"

the Examiner appears to suggest that knowledge of the entire sequence of a full-length opioid receptor is required to practice the claimed invention. However, this is not the case. The claims only pertain to binding of the substance to the recombinant opioid receptor polypeptide encoded by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:1 1. The Examiner appears to be arguing for inadequate written description support for a limitation that is not present in the claims at issue and that "consisting of" or "comprising up to" language is not required.

These arguments have been considered, but are not deemed persuasive. Applicants general argument is that they have provided adequate written description of SEQ ID NO:11 and that the claims are drawn to SEQ ID NO:11. Therefore, Applicants deserve claims which read on methods which encompass the full length receptor comprising SEQ ID NO:11. The way the claims are worded they are, in fact, "reach through" claims. The Examiner is not questioning the fact that Applicants were in possession of SEQ ID NO:11, or fragments of SEQ ID NO:11. The issue, as also understood by Applicants is that Applicants are not in possession of the full-length protein comprising more than the bases of SEQ ID NO:11. SEQ ID NO:11 encodes a partial receptor sequence and nowhere in the specification do Applicants disclose that they were in possession of the sequence of the entire opioid receptor encoded by a polynucleotide greater than SEQ ID NO:11. Applicants have only disclosed SEQ ID NO:11 and, therefore, the claims should reflect this. Therefore, since Applicants were in possession of SEQ ID NO:11 at the time of the present invention, they would be entitled to claims which encompass up to the full length of SEQ ID NO:11. Applicants should not be entitled to claims reading on the full length opioid receptor when they were not in possession of it at the time of the present invention. One of ordinary skill in the art would not appreciate the fact that Applicants were in possession of the claimed invention, which includes the full-length opioid receptor encompassed by the currently claimed invention. It is believed that all pertinent arguments have been addressed.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 97-102 remain rejected and new claims 144-156 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-4 of the Office Action dated 6/17/03. Applicants argue that substantial information pertaining to processes for screening a substance for its ability to specifically bind an opioid receptor can be found throughout the specification. The entire polynucleotide sequence of SEQ ID NO:11 is found in the specification. Examples 1-8 provides substantial information pertaining to opioid receptors and opioid receptor polypeptides, opioid receptor isolation, and opioid

receptor binding studies and Example 10 provides information pertaining to the binding domains of the kappa receptor, and assays for binding to the receptor. Applicants argue that even though they are not required to disclose a full-length human opioid receptor to enable the claimed invention, they do so. The process, rather than requiring use of a full-length human opioid receptor polynucleotide sequence, pertains to polynucleotides that are encoded by at least 30 contiguous bases of SEQ ID NO:11. The specification fully discloses SEQ ID NO:11 and that knowledge of a full-length opioid receptor sequence is not required to practice the claimed invention. However, Applicants argue that the specification fully enables Applicants' claimed process, which pertains to SEQ ID NO:11 and not the entire sequence of a full-length opioid receptor. Disclosure of the entire sequence of a full-length opioid receptor in the specification is not required for one of skill in the art to recognize the invention. Finally, Applicants argue that no where in the claim is there a recitation of a requirement that it must be determined whether the substance is an agonist or an antagonist of the receptor. Rather, the claims only pertain to binding of the substance to the recombinant opioid receptor polypeptide encoded by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:11. The Examiner appears to be arguing for inadequate enablement for a limitation that is not present in the claims at issue.

These arguments have been considered, but are not deemed persuasive. Applicants general argument is that they have enabled what they have claimed, which are methods comprising SEQ ID NO:11 and that the claims are drawn to SEQ ID NO:11. Therefore, Applicants deserve the breadth of these claims even though they read on methods which encompass the full length receptor comprising SEQ ID NO:11. The way the claims are worded they are, in fact, "reach through" claims. The Examiner is not questioning the fact that Applicants are not entitled to the breadth of the claims encompassing SEQ ID NO:11, or fragments of SEQ ID NO:11. The issue, as also understood by Applicants is that the claims read on the full-length protein comprising more than the bases of SEQ ID NO:11. SEQ ID NO:11 encodes a partial receptor sequence and nowhere in the specification do Applicants disclose that they have enabled the use of the entire opioid receptor encoded by a polynucleotide greater than SEQ ID NO:11. Applicants have only disclosed SEQ ID NO:11 and, therefore, the claims should reflect this. Applicants argue that Examples 1-8 provides substantial information pertaining to opioid receptors and opioid receptor polypeptides, opioid receptor isolation, and opioid receptor binding studies and Example 10 provides information pertaining to the binding domains of the kappa receptor, and assays for binding to the receptor. However, this still does not provide enablement for the full-length protein encoded by a polynucleotide greater than SEQ ID NO:11. Therefore, since Applicants only provided guidance and working examples of methods using SEQ ID NO:11 at the time of the present invention, they would be

entitled to claims which encompass up to the full length of SEQ ID NO:11. Applicants should not be entitled to claims reading on the full-length opioid receptor when they have not provided guidance and working examples of the full-length receptor at the time of the present invention. Furthermore, it would not have been predictable to one of ordinary skill in the art at the time of the present invention what the sequence is of the full-length receptor. It is believed that all pertinent arguments have been addressed.

4. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdraw in view of Applicants' arguments, or amendments to the claims regarding identifying agonists via a functional assay and isolating the potential agonist.

5. Conclusion

A. Claims 109,112-114,123 and 144-150 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 22, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600